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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/801,443 | 03/15/2004 | Om Dutt Tyagi | 11336.0020US01 | 2004 |
| 23552 | 7590 | 03/10/2006 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | BERCH, MARK L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| DATE MAILED: 03/10/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/801,443 | Applicant(s) TYAGI ET AL. | |
| | Examiner Mark L. Berch | Art Unit 1624 | |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/21/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, drawn to Synthesis of cefprozil, classified in class 540, subclass 215.
- II. Claim 29-30, drawn to anhydride, classified in class 562, subclass 887, 894.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of manufacture and a reagent used in the process. The groups are distinct, in that the reagent can be used in a different process, e.g. a process of making a penicillin derivative. Moreover, the process does not require this reagent, as the starting material can be converted into the final product by means of other acylating agents, such as are known in the art for the synthesis of cefprozil.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Skoog on 1/26/2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6903211.

The reference teaches the same process as applicants have. See Scheme 2, reaction of XII with XIII (which itself anticipates claim 28) to give I. This is the DMF solvate. The reference teaches converting that to cefprozil monohydrate itself at column 4, lines 1-3. See for example 1, step (vi), which prepares the DMF solvate, and step (vii) which converts this to the monohydrate.

The claims do not actually recite the use of a DMF solvate as intermediate. However, the claims are written in “comprising” form, so that the claims are embrative of any additional step, including such a step. Page 20 teaches that the use of DMF solvate as intermediate is preferred. And that is exactly what was done in both examples. Hence, applicants have the exact same process.

Claims 2 and 3 have a step in which the acylating agent and the base are mixed at no cooler than 0oC and then chilled, all prior to being exposed to the Dane salt. That is not suggested by the reference. In addition, claim 2 requires two solvents for this, and claim 3 entails one solvent, but solvent is not used in the reference. Moreover, claim 3 has the additional step of adding a polar aprotic solvent after the reactants have all been mixed, which is again not suggested by the reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The variable R is not defined in claim 1.
2. "Substantially Free" is indefinite. There is no way of knowing exactly what level of purity this entails.
3. Likewise for "high yield". What does this require?
4. "Preferably" (e.g. temperatures in claim 2-3, ratios in claims 13-18, etc.) is improper alternative language (In re Kingston, 65 USPQ 371). Likewise "preferred" in claim 7-12 etc.
5. The same applies to "like" in claims 9-10, etc.
6. Claim 4 is unclear. The (VI) formula shows methyl groups attached to Si, but the R3/R4 definition says "alkyl". Which is it?
7. The entire business of "include" in e.g. claims 9-10 is unclear. Is this a claim limitation? If not, it needs to be removed.

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8. The term "7-APCA" in claims 25-27 needs a definition.

Claims 2-3, 5-24 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The term "an acylating agent" in claim 2-3 is simply not correct (paragraph 2), and is not enabled for such scope (paragraph 1). Acetic acid is an extremely common acylating agent and it obviously will not work. As a practical matter, it has to be an agent which will attach a -C(O)OR₃ group, e.g. chloroformates.

Claim Objections

Claims 6, 8, 18, 20, 22, 24, and 28 lack final periods.

Claim 16 ends in two periods

Claim 6 should have "chloroethane".

Claim 7 has a period in middle of claim.

Specification

The second line of the abstract is missing text.

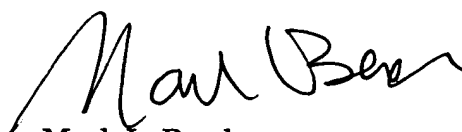
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Mark L. Berch". The signature is fluid and cursive, with the first name "Mark" being more prominent than the last name "Berch".

Mark L. Berch
Primary Examiner
Art Unit 1624

3/2/06